UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JANE PLATTEN,

Plaintiff,

and

DEAN HEALTH PLAN,

Involuntary Plaintiff,

v. Case No. 20-C-1265

SMITH & NEPHEW INC.,

Defendant.

DECISION AND ORDER

On March 28, 2017, Plaintiff Jane Platten underwent revision surgery on her left hip to repair a failed ceramic-on-ceramic hip replacement system. The ceramic acetabular liner component of the system had fractured after only six years. Rather than replace the entire system, Plaintiff's orthopedic surgeon elected to replace the ceramic acetabular liner and the ceramic femoral head components with a cross-linked polyethylene (XLPE) liner and a cobalt-chromium (CoCr) femoral head designed and manufactured by Smith & Nephew. Plaintiff alleges that Smith & Nephew knew of but failed to warn Plaintiff and the medical community, including her orthopedic surgeon, of the increased risk of metal toxicity associated with implanting a CoCr femoral head in conjunction with an XLPE acetabular liner during a revision surgery following the fracture of a ceramic component. Plaintiff alleges that, following her revision surgery, she suffered from cobalt poisoning caused by the defective configuration of the CoCr femoral head against the XLPE acetabular liner due to the femoral head grinding against trapped ceramic

particles ingrained in the XLPE liner. The cobalt poisoning is alleged to have caused Plaintiff significant and lasting vision loss, hearing loss, cardiomyopathy, neuropathy, and skin cancer.

Based on these allegations, Plaintiff sued Smith & Nephew, Inc., a Delaware corporation with its principal place of business in Tennessee, and two foreign entities, Smith & Nephew Ltd. and Smith & Nephew PLC, in the Circuit Court for Brown County, Wisconsin. Although Plaintiff states in the "Introduction" to her complaint that "[t]his is a products liability action," Compl. at 1, Dkt. No. 1-1 at 7, there is no separate claim designated "Product Liability" or "Strict Liability." Instead, the complaint identifies five different claims for relief: (1) negligence and negligent failure to warn, (2) negligence *per se*, (3) breach of express warranty, (4) breach of implied warranty, and (5) negligent misrepresentation. Smith & Nephew, Inc., and Smith & Nephew Ltd. removed the case from Brown County Circuit Court to federal court. Dkt. No. 1. As explained below, this court has jurisdiction under 28 U.S.C. § 1332(a). Presently before the court is the defendants' motion for partial summary judgment, Dkt. No. 30. Based on the stipulation of the parties, all claims against defendants Smith & Nephew Ltd. and Smith & Nephew PLC have been dismissed with prejudice. As for the remaining defendant, Smith & Nephew, Inc. (hereinafter, "Smith & Nephew"), the motion for partial summary judgment will be granted but only in part. The court begins with a statement of the facts viewed in the light most favorable to Plaintiff, as is required in deciding a motion for summary judgment. Fed. R. Civ. P. 56.

BACKGROUND

After experiencing severe and chronic hip pain, Plaintiff underwent an arthroscopic procedure on her left hip in May 2010. The procedure did not relieve her pain, however. Def.'s Statement of Proposed Material Facts (DSOPMF) ¶¶ 1–2, Dkt. No. 32. On March 8, 2011, Plaintiff underwent a total hip arthroplasty (THA) of her left hip. *Id.* ¶ 3. The medical device components

implanted during that hip replacement procedure were manufactured and sold by Smith & Nephew and included an R3 acetabular shell, a Reflection central hole cover, a Biolox Forte ceramic acetabular liner, an Anthology femoral stem, and a Biolox Forte ceramic femoral head. *Id.* ¶ 5. The following illustration depicts the general type of medical device components that are implanted during a THA:

Id. ¶ 4.

Shortly after Plaintiff's surgery, Smith & Nephew issued a recall for the ceramic liner component used in her arthroplasty due to some small number of patients experiencing cracking and failure of the liner. Pl.'s Supplemental Statement of Facts (PSSOF) ¶ 4, Dkt. No. 52-2. Neither Plaintiff, nor her surgeon, were aware of the recall. About six years after the procedure, Plaintiff experienced pain in her left hip shortly after dismounting a horse. She felt and heard a pop in her hip as she was walking down a carpeted hotel hallway the following day. DSOPMF ¶¶ 9–11. X-rays revealed potential problems with the ceramic acetabular liner and/or ceramic femoral head components of the implant, and it was later determined that the ceramic acetabular liner had fractured. *Id.* ¶¶ 12–13.

On March 22, 2017, Plaintiff had an appointment with Dr. Matthew Colligan, an orthopedic surgeon who specializes in hip replacements. *Id.* ¶¶ 14–15. Dr. Colligan recommended revision surgery and discussed with Plaintiff the general risks of such a procedure, including pain, infection, nerve and vessel injury, dislocation, and weakness. *Id.* ¶¶ 17–18. On March 28, 2017, Dr. Colligan performed revision surgery on Plaintiff's left hip at St. Mary's Hospital in Green Bay, Wisconsin. *Id.* ¶ 27. Dr. Colligan removed the fractured ceramic liner and the ceramic femoral head components of Plaintiff's total hip replacement device and replaced those ceramic components with a Smith & Nephew XLPE polyethylene acetabular liner and CoCr femoral head. Plaintiff's existing acetabular shell and the femoral stem components were left in place. *Id.* ¶¶ 28–30. The components Dr. Colligan used in the revision surgery were sold by Smith & Nephew to St. Mary's Hospital. *Id.* ¶ 32. Plaintiff did not purchase those components herself. She did not conduct independent research regarding the type of implanted components that would be used for her revision surgery but instead trusted and relied upon Dr. Colligan's medical judgment to make the best and, all things considered, most appropriate decisions regarding her care. *Id.* ¶¶ 33–34.

Smith & Nephew publishes surgical-technique brochures that discuss the process and instructions for implanting Smith & Nephew components used in surgery. *Id.* ¶ 35. Smith & Nephew has offered into evidence the 2016 Surgical Technique brochure that was available at the time of Plaintiff's revision surgery in March 2017. That version recommended against the use of a metal or Oxinium femoral head component for a revision surgery that was necessitated by the fracture of a ceramic component, stating in relevant part:

> [I]n the case of revision due to ceramic fracture of ceramic components (ceramic ball head or ceramic liner), it is recommended that neither metal nor OXINIUM ball heads be used as remaining fragments increase the risk of accelerated wear and reduced implant life of the replacement ball heads and polyethylene liner. This will necessitate the removal and replacement of the femoral component to provide a

> suitable femoral taper to attach the new ceramic ball head with corresponding polyethylene liner and metal shell.

Id. ¶ 36. Smith & Nephew also issued an Advisory Notice dated June 2, 2016, which advised against the use of metal or polyethylene components during a revision surgery for a fractured ceramic component. *Id.* ¶ 44. Like the Surgical Technique brochure, the Advisory Notice warned of "premature wear of revision components if such components are made of non-ceramic materials." Anthony Monaco Decl., Ex. H, Advisory Notice at 2, Dkt. No. 33-8. The Notice stated: "This can lead to the need for additional revision surgery." *Id.* It said nothing of the risk of permanent impairment or even death resulting from metal toxicity. Plaintiff does not dispute the authenticity of the Surgical Technique brochure and Advisory Notice but notes that earlier versions of the brochure did not contain such advice and contends that it is unclear when the 2016 version and Advisory Notice were published and distributed to physicians in the field. Pl.'s Resp. to DSOPMF ¶ 44, Dkt. No. 44.

In any event, Dr. Colligan did not review any surgical-technique brochure before he performed Plaintiff's revision surgery and was unaware of the Advisory Notice. *Id.* ¶ 41; DSOPMF ¶ 37. Smith & Nephew also publishes Instructions for Use (IFUs) that accompany all components that it manufactures. The IFUs discuss the risks and warnings relevant to each of the medical device components and are included in every box of components, but the record does not contain the actual IFUs that accompanied the Smith & Nephew components Dr. Colligan implanted during the revision surgery. DSOPMF ¶¶ 38–39. Dr. Colligan did not read or rely upon the specific IFU for the components he ultimately used for Plaintiff's revision surgery, and he was not aware that IFUs were enclosed with boxes containing Smith & Nephew medical components because he was not responsible for opening such boxes; that task was performed by hospital personnel. *Id.* ¶ 40.

Smith & Nephew, like other medical implant device companies, has distributors that employ sales representatives who sell its products and interact with the hospitals that purchase and the surgeons who implant them. The sales representative for Smith & Nephew devices in northeast Wisconsin in 2017 was Jon Bjelde. Monaco Decl., Ex. C, Jon Bjelde Dep. at 16–21, 24, 26, Dkt. No. 33-3. Typically, the sales representative is notified by the hospital of scheduled surgeries and consults with the surgeon about the implant devices that may be needed. Mr. Bjelde was usually present during the surgery to make sure that the Smith & Nephew products needed to complete the surgery were available. With respect to Plaintiff's revision surgery, Mr. Bjelde was notified of the need to perform the revision due to a ceramic failure. According to Mr. Bjelde, he informed Dr. Colligan that Smith & Nephew has advised that in the case of a revision due to failure of a ceramic component, the surgeon should do a more extensive revision and put a fresh ceramic head on a new femoral stem. *Id.* at 66:04–69:25. Nevertheless, Mr. Bjelde provided Dr. Colligan with the CoCr femoral head that he requested.

Dr. Colligan denied that Mr. Bejelde had told him that a ceramic head should be used in the revision surgery. Monaco Decl., Ex. B, Matthew Colligan Dep. at 156:11–57:22, Dkt. No. 33-2 at 41. At the time of Plaintiff's revision surgery, Dr. Colligan believed the standard of care for revision of a failed ceramic hip implant cautioned against replacing ceramic with ceramic. Because the ceramic implant had failed, Dr. Colligan suggested, a physician was not inclined to use ceramic again. While he knew of some isolated case studies of metal toxicity with conversion over to metal, Dr. Colligan was not aware of a consensus recommending against metal components as a new standard of care. DSOPMF ¶ 41; Colligan Dep. at 20:20–21:07. Dr. Colligan indicated that he took the risk of metal toxicity into account when deciding which components to use in Plaintiff's revision. He balanced that risk against the risks associated with removing the well-fixed

acetabular and femoral components and installing all new components, instead of just the acetabular liner and femoral ball. Based on the information he had, Dr. Colligan believes he made a reasonable decision. DSOPMF ¶ 43. Had he known, however, that Smith & Nephew had warned against implanting a CoCr femoral head after a ceramic component fracture in its Surgical Technique brochure and in an Advisory Notice, Dr. Colligan would not have used those components for Plaintiff's revision surgery. PSSOF ¶ 68. And had he received the Advisory Notice after the surgery, Dr. Colligan would have alerted Plaintiff and advised her to have her metal ion levels tested more frequently. *Id.* ¶ 72.

In the months following the March 28, 2017, revision surgery, Plaintiff began to experience symptoms of fatigue, aches, and pain. In 2018, she experienced continued fatigue; hair, vision, and hearing loss; headaches; numbness; and paresthesia; and she was diagnosed with hypothyroidism, sinus tachycardia, cardiomyopathy, and congestive heart failure. *Id.* ¶ 73. Because she was not experiencing hip pain, the doctors who were treating Plaintiff for these various maladies did not attribute them to the revision surgery. As her condition worsened, however, Plaintiff's daughter happened to see a documentary that described the systemic effects of cobalt toxicity that occurs in some rare cases of THA failure and urged her mother to alert her doctors to the possibility that her hip surgery may be the source of her symptoms. Monaco Decl., Ex. I, David Lewallen Dep. at 10:12–12:10, Dkt. No. 33-9. Laboratory tests showed the level of cobalt in Plaintiff's blood to be extremely high, and Plaintiff was immediately referred to Dr. David Lewallen of the Mayo Clinic, who specializes in hip and knee arthroplasty, especially revision surgery. *Id.* at 6:25–7:5. Given the risks of further deterioration and even death, Plaintiff was scheduled for surgery as quickly as possible. On August 10, 2018, Plaintiff underwent a second revision surgery, performed by Dr. Lewallen, during which the Smith & Nephew

polyethylene liner and the metal femoral head components were removed and replaced with a new ceramic liner and a ceramic femoral head. DSOPMF ¶ 50.

Dr. Lewallen indicated that, if a patient had presented to him with a fractured ceramic component at Mayo Clinic in March 2017, when Plaintiff had her revision surgery, he would have known that it was not advisable to implant a CoCr femoral head following a ceramic component fracture. *Id.* ¶ 52. He also acknowledged, however, that the problem of ceramic particles serving as an abrasive after a fracture in a THA "is not as widely recognized as it should be and certainly was less well-known . . . back in 2017, 2018." Lewallen Dep. at 18:11–13. Explaining further, Dr. Lewallen stated that he had never seen such a case or heard of one at Mayo, but he was aware of "anecdotal stories about cases like this both as isolated case reports in the literature and from stories from friends of ours in Europe where they had people over there that had . . . a case or two of this being reported from here and there." *Id.* at 18:20–25.

LEGAL STANDARD

Summary judgment shall be granted when the movant shows that there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In deciding a motion for summary judgment, the court must view the evidence and make all reasonable inferences from it in the light most favorable to the nonmoving party. *Johnson v. Advocate Health & Hosps. Corp.*, 892 F.3d 887, 893 (7th Cir. 2018) (citing *Parker v. Four Seasons Hotels, Ltd.*, 845 F.3d 807, 812 (7th Cir. 2017)). The party opposing the motion for summary judgment must "submit evidentiary materials that set forth specific facts showing that there is a genuine issue for trial." *Siegel v. Shell Oil Co.*, 612 F.3d 932, 937 (7th Cir. 2010) (citations omitted). "The nonmoving party must do more than simply show that there is some metaphysical doubt as to the material facts." *Id.* Summary judgment is properly entered against a party "who

fails to make a showing to establish the existence of an element essential to the party's case, and on which that party will bear the burden of proof at trial." *Austin v. Walgreen Co.*, 885 F.3d 1085, 1087–88 (7th Cir. 2018) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

ANALYSIS

A. Subject Matter Jurisdiction

As an initial matter, the court must determine that it has subject matter jurisdiction over the case before it. *See Lear Corp. v. Johnson Elec. Holdings Ltd.*, 353 F.3d 580, 582 (7th Cir. 2003) ("Neither the parties nor the district judge devoted much attention to what must be the first issue in every federal suit: subject-matter jurisdiction."). Smith & Nephew and Smith & Nephew Ltd. removed this action from Brown County Circuit Court to this court, asserting federal jurisdiction under 28 U.S.C. § 1332. There is a problem, however, with the defendants' jurisdictional allegations. Two of the named defendants, Smith and Nephew PLC and Smith and Nephew Ltd., are foreign business entities. In its Notice of Removal, the defendants alleged that Smith & Nephew Ltd. was "a corporation organized under the laws of the United Kingdom" with its principal place of business located in the United Kingdom. Dkt. No. 1 at 4. The Notice alleged that Smith & Nephew PLC was "a company organized and existing under the laws of England and Wales with its principal place of business in London, England." *Id.* In other words, the Notice of Removal "assumes that that [the United Kingdom] has business entities that enjoy corporate status as the United States understands it." *White Pearl Inversiones S.A. (Uruguay) v. Cemusa, Inc.*, 647 F.3d 684, 686 (7th Cir. 2011). "Yet," as the court explained in *White Pearl*, "not even the United Kingdom has a business form that is exactly equal to that of a corporation." *Id.* By way of example, the court noted that "it can be difficult to decide whether a business bearing the suffix

'Ltd.' is a corporation for the purpose of § 1332 or is more like a limited partnership, limited liability company, or business trust." *Id.*

This court addressed jurisdiction at a September 25, 2020, scheduling conference. Though Smith & Nephew PLC had not yet been served, the court was assured by counsel that each of the foreign business entities was not in fact a citizen of Wisconsin and that complete diversity jurisdiction existed. When the proposed findings of fact submitted by Smith & Nephew in support of its motion for partial summary judgment did not substantiate that assertion, the court directed the parties to supplement the record. Dkt. No. 61. They have done so in two ways.

First, the parties have stipulated to the dismissal with prejudice of Smith & Nephew Ltd. and Smith & Nephew PLC, with the understanding that the case would continue against Smith & Nephew, Inc., which the Notice of Removal identified as a corporation organized under the laws of the State of Delaware with its principal place of business in Tennessee. Dkt. No. 1 at 4. Based on the parties' stipulation, the court ordered Smith & Nephew Ltd. and Smith & Nephew PLC dismissed, and thus it is now clear that complete diversity exists. To demonstrate that subject matter jurisdiction also existed at the time the case was removed, Smith & Nephew has also submitted in response to the court's order an affidavit by Sarah Carne, the Deputy Company Secretary for Smith & Nephew PLC, in which Ms. Carne describes the structure and operations of Smith & Nephew PLC, as well as those of its direct and indirect subsidiaries, including Smith & Nephew, Inc., and Smith & Nephew Ltd. Based upon Ms. Carne's affidavit, the court is satisfied that none of the original defendants is a citizen of the State of Wisconsin and that subject matter jurisdiction under 28 U.S.C. § 1332 has existed from the time the case was removed. Having determined that subject matter jurisdiction exists, the court now turns to the motion before it.

B. Breach of Express and Implied Warranty

In her complaint, Plaintiff alleges that Smith & Nephew violated express warranties that the medical device components were of merchantable quality, fit for the ordinary purposes and uses for which they were sold, and could be used together in a safe and effective way. She also alleges that Smith & Nephew violated implied warranties of merchantability and fitness for a particular purpose. In support of its motion for partial summary judgment, Smith & Nephew argues that Plaintiff's breach of warranty claims must be dismissed because there is no privity between Plaintiff and Smith & Nephew.

The parties agree that Wisconsin law governs this case. *See* Def.'s Br. at 8 n.9, Dkt. No. 31. "Wisconsin law requires privity of contract between the parties before liability can be founded on breach of express or implied warranty." *St. Paul Mercury Ins. Co. v. The Viking Corp.*, 539 F.3d 623, 626 (7th Cir. 2008) (citation omitted). Privity of contract is the connection or relationship that exists between two or more contracting parties. *City of La Crosse v. Schubert, Schroeder & Assocs.*, 72 Wis. 2d 38, 41, 240 N.W.2d 124 (1976), *overruled on other grounds by Daanen & Janssen, Inc. v. Cedarapids, Inc.*, 216 Wis. 2d 395, 397, 573 N.W.2d 842 (1998). "The elements of an enforceable contract are offer, acceptance, and consideration. . . . The existence of an offer and acceptance are mutual expressions of assent, and consideration is evidence of the intent to be bound to the contract." *Runzheimer Int'l, Ltd. v. Friedlen*, 2015 WI 45, ¶ 20, 362 Wis. 2d 100, 862 N.W.2d 879 (citations omitted).

Plaintiff cites *Sunnyslope Grading, Inc. v. Miller, Bradford and Risberg, Inc.*, 148 Wis. 2d 910, 437 N.W.2d 213 (1989), for the proposition that "[i]n Wisconsin, a buyer can pursue a contract claim against a non-seller manufacturer of goods for a claim for breach of the manufacturer's express warranty." Pl.'s Br. in Opp'n at 24, Dkt. No. 42. But *Sunnyslope* does

not stand for the proposition that privity is not required for a breach of warranty claim. In *Sunnyslope*, the purchaser bought the allegedly defective product, a backhoe, through the manufacturer's dealer. 148 Wis. 2d at 913. The manufacturer expressly offered a warranty to the purchasers of its products, including those who purchased through dealers, and Sunnyslope, the purchaser, implicitly accepted the terms of the warranty when it accepted repairs under it. Because they were parties to an enforceable warranty, the court concluded that Sunnyslope and the manufacturer were in privity. *Id.* at 915. "Privity," the court held, "is nothing more than the relationship between the parties to a contract and follows from the fact that a contract exists." *Id.* at 916.

In this case, Smith & Nephew was not in a contractual relationship with Plaintiff. Plaintiff has offered no evidence that Smith & Nephew offered a warranty to the purchasers of its products. In any event, the medical components that Dr. Colligan used in Plaintiff's revision surgery were sold by Smith & Nephew to St. Mary's Hospital, not to Plaintiff or her physician. DSOPMF ¶ 32. Plaintiff did not see or receive any purported warranty or other statement from Smith & Nephew regarding the components to be used in her revision surgery; indeed, Plaintiff stated that she trusted and relied upon Dr. Colligan's medical judgment to make the appropriate decisions regarding her care, including which components to implant during the revision surgery of her left hip. *Id.* ¶ 34. Plaintiff did not undertake any independent research regarding the components to be used. *Id.* Therefore, there is no basis upon which to conclude that Plaintiff and Smith & Nephew were in privity of contract, which means that Plaintiff's breach-of-warranty claims cannot proceed. *See St. Paul Mercury Ins. Co.*, 539 F.3d at 625, 628 (affirming summary judgment for the defendant manufacturer where there was no privity of contract between the parties, and there was no evidence that the plaintiff ever received any warranty information, advertising, or other literature from the

defendant regarding the product at issue). Accordingly, Plaintiff's claims of breach of express warranty and breach of implied warranty are dismissed.

C. Product Liability

Plaintiff argues alternatively that her breach of implied warranty claim should be recognized as a strict liability claim. Pl.'s Br. in Opp'n at 25. Under the doctrine of strict or product liability, the manufacturer or seller of a defective product that is unreasonably dangerous to the user or consumer is liable for any injuries or damages resulting from the intended use of the product without regard to the negligence of the manufacturer or seller. *Dippel v. Sciano*, 37 Wis. 2d 443, 459, 155 N.W.2d 55 (1967). Under Wisconsin law, "[a] product is defective because of inadequate instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). As noted above, although the complaint states in its "Introduction" that "[t]his is a products liability action," Compl. at 1, none of the five claims are labeled product or strict liability.

Smith & Nephew argues in its reply brief that "Plaintiff may not convert her implied warranty claim to a strict liability claim." Def.'s Reply Br. at 6, Dkt. No. 54. If Plaintiff wishes to add a claim for strict liability, Smith & Nephew contends, she must proceed under Rule 15 of the Federal Rules of Civil Procedure and seek to amend her complaint. Citing *Bethany Pharmacal Co., Inc. v. QVC, Inc.*, 241 F.3d 854 (7th Cir. 2001), which affirmed a district court's decision denying a motion to amend filed in response to a motion for summary judgment, Smith & Nephew argues that Plaintiff may not amend her complaint at this late date.

But Plaintiff has not asked to amend her complaint to add a claim for strict liability; she asks that her claim for breach of implied warranty be "recognized as a strict liability claim." Pl.'s Br. in Opp'n at 25. The issue before the court is therefore whether the allegations of her complaint, reasonably read, state a claim for strict liability. "Once the case has been removed, the complaint is subject to federal pleading rules." *Nipponkoa Ins. Co., Ltd. v. GlobeGround Servs., Inc.*, No. 04 C 5648, 2007 WL 2410292, at *5 (N.D. Ill. Aug. 17, 2007) (citing *Rossario's Fine Jewelry, Inc. v. Paddock Publ'ns, Inc.*, 443 F. Supp. 2d 976, 978 (N.D. Ill. 2006)). "Under federal pleading rules, a plaintiff is not limited to nor bound by the legal characterizations contained in the complaint." *Id.* To state a claim under federal pleading rules, "[a] complaint must narrate a claim, which means a grievance such as 'the City violated my rights by preventing me from renovating my apartments.'" *Albiero v. City of Kankakee*, 122 F.3d 417, 419 (7th Cir. 1997). "Having specified the wrong done to him, a plaintiff may substitute one legal theory for another without altering the complaint." *Id.*; *see also Health Care Indus. Liab. Ins. Program v. Momence Meadows Nursing Ctr., Inc.*, 566 F.3d 689, 696 (7th Cir. 2009) ("Momence is correct that the factual allegations in the complaint, and not the legal labels a plaintiff uses, control.").

Applying these principles to the facts of this case, the court is satisfied that the allegations of the complaint are more than sufficient to state a claim for strict liability under Wisconsin law. At oral argument, Smith & Nephew essentially agreed. As Smith & Nephew notes at the outset of its brief in support of its motion for partial summary judgment, "[t]he common thread in each Count is that Smith & Nephew allegedly failed to warn Plaintiff and the medical community, including Plaintiff's surgeon, of the risks associated with implanting a CoCr femoral head in conjunction with an XLPE acetabular liner during a revision surgery following the fracture of a ceramic component." Def.'s Br. at 2. Plaintiff even begins her complaint with the statement "[t]his

is a products liability action." Compl. at 1. The specific allegations of the complaint narrate a claim that Smith & Nephew failed to provide the warnings needed to reduce or avoid the foreseeable risks of harm posed by the use of its product under the circumstances presented by Plaintiff's condition. The court therefore concludes that Plaintiff's complaint states a product liability claim against Smith & Nephew.

D. Failure to Warn

As noted above, Smith & Nephew recognizes that "[t]he common thread in each Count [of Plaintiff's complaint] is that Smith & Nephew allegedly failed to warn Plaintiff and the medical community, including Plaintiff's surgeon, of the risks associated with implanting a CoCr femoral head in conjunction with an XPLE acetabular liner during a revision surgery following the fracture of a ceramic component." Def.'s Br. at 2. Under Wisconsin law, there are three elements to a failure to warn claim: "(1) existence of a duty to warn; (2) proof of a failure to warn adequately; and (3) proof of causation of injury." *Schreiner v. Wieser Concrete Prods., Inc.*, 2006 WI App 138, ¶ 8, 294 Wis. 2d 832, 720 N.W.2d 525 (citing *Kurer v. Parke, Davis, & Co.*, 2004 WI App 74, ¶ 24, 272 Wis. 2d 390, 679 N.W.2d 867).

Plaintiff contends that long before her revision surgery in March 2017, Smith & Nephew knew, or should have known, as it warned in its June 2016 Surgical Technique brochure and Advisory Notice, that physicians should not use a metal femoral head to replace a ceramic head in a revision surgery following the fracture of a ceramic component. Smith & Nephew explained in its brochure that the remaining fragments from the ceramic components "increase the risk of accelerated wear and reduced implant life of the replacement ball heads and polyethylene liner." DSOPMF ¶ 36. Plaintiff has also offered expert testimony in support of her allegation that Smith & Nephew knew or should have known of the increased risk of metal toxicity resulting from

replacement of a ceramic with a metal ball, especially a CoCr ball, after the failure of a ceramic component of a hip replacement system. Mari Truman Decl., Dkt. Nos. 46-6, 52-3; George Kantor, M.D., Decl., Dkt. Nos. 46-7, 52-4.

1. Learned Intermediary Doctrine

Smith & Nephew contends that Plaintiff's failure to warn claim nevertheless fails. Plaintiff's claim is barred, Smith & Nephew first argues, by the learned intermediary doctrine. The learned intermediary doctrine holds that "the manufacturer of a prescription drug or medical device fulfills its duty to warn of the product's risks by informing the prescribing physician of those risks." *In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 751 (7th Cir. 2018). Although neither the Wisconsin Supreme Court nor the state's intermediate appellate courts have addressed the doctrine, the Seventh Circuit has held that the state's high court is likely to do so when presented with the opportunity and thus considered it the law in Wisconsin. *Id.* at 751–52. This court is bound by that determination and will therefore proceed to apply that doctrine here.

Notwithstanding the fact that the learned intermediary doctrine applies in Wisconsin, Smith & Nephew is not entitled to summary judgment on Plaintiff's failure to warn claim under that doctrine. The doctrine only bars a failure to warn claim where the evidence establishes that the required warnings were given to the learned intermediary, in this case, Dr. Colligan. There is a factual dispute, however, over whether Dr. Colligan was ever warned of the increased risk of metal toxicity attendant upon using a CoCr femoral head after the failure of a ceramic component of a hip replacement system. Although Smith & Nephew revised its Surgical Technique brochure and sent out an Advisory Notice cautioning surgeons against using a metal femoral head in revision surgery necessitated by the failure of a ceramic component, it is not clear from the evidence that

the warnings were adequate or adequately distributed, given the risk involved. Smith & Nephew warned only of increased wear of the components which could result in a need for further revision. Smith & Nephew said nothing about the kind of systemic and life-threatening damage to other organs that Plaintiff experienced as a result of the cobalt poisoning caused by the CoCr femoral ball that was used in her revision surgery.

Plaintiff has offered evidence that Smith & Nephew was aware, or should have been aware, of this risk long before its 2016 revisions to its Surgical Technique brochure and Advisory Notice. Mari Truman, a biomedical engineer with 41 years of experience in the biomechanics and orthopedic fields, states in her report that Smith & Nephew should have advised surgeons of the hazards of using CoCr heads with XLPE liners after a ceramic failure no later than 2014. Andrew Schwaba Supp. Decl., Ex. 6, Truman Report at 39, Dkt. No. 52-3. According to Ms. Truman, Smith & Nephew also should have advised physicians to rigorously monitor cobalt levels of patients should a CoCr head be used with an XLPE liner after a ceramic failure. *Id.*

Ms. Truman also concluded that the warnings Smith & Nephew did provide were not adequately distributed to the surgeons and hospitals that were performing the revision surgeries, considering the life-threatening nature of the risks associated with using CoCr heads in revisions following ceramic failures. There is evidence that neither Dr. Colligan, nor St. Mary's Hospital, where Plaintiff's surgery was performed, received the Surgical Technique brochure or the Advisory Notice. A reasonable and prudent manufacturer of implant components, Ms. Truman opines, would have sent letters directly to surgeons performing such surgeries and had systems in place to assure its sales and service representatives were made aware of the contraindications for using CoCr femoral heads in such situations and the magnitude of the risk. *Id.* Given this

evidence, Smith & Nephew is not entitled to summary judgment based on the learned intermediary doctrine.

2. Sophisticated User Doctrine

Smith & Nephew next argues that Plaintiff's failure to warn claim is barred by Wisconsin's sophisticated user doctrine. The sophisticated user defense is based upon the RESTATEMENT (SECOND) OF TORTS § 388, which "addresses the duty of a manufacturer to warn in negligence actions" and provides that "manufacturers are under a duty to warn only if the manufacturer has no reason to believe that the user will realize the item's dangerous condition." *Strasser v. Transtech Mobile Fleet Serv., Inc.*, 236 Wis. 2d 435, 460, 613 N.W.2d 142 (2000) (quoting RESTATEMENT (SECOND) OF TORTS § 388(b)); *see Burton v. Am. Cyanamid Co*, 441 F. Supp. 3d 705, 718 (E.D. Wis. 2020), *reversed on other grounds*, 994 F.3d 791 (7th Cir. 2021). The doctrine generally holds that "there is no duty to warn members of a trade or profession about dangers generally known to the trade or profession." *Shawver v. Roberts Corp.*, 90 Wis. 2d 672, 686, 280 N.W.2d 226 (1979). In *Haase v. Badger Mining Corp.*, the court explained the policy reasons supporting the adoption of the sophisticated user defense:

> First, it places the duty to warn on the party arguably in the best position to ensure workplace safety, the purchaser-employer. Second, the burden falls upon the party in the best position to know of the product's potential uses—thereby enabling that party to communicate safety information to the ultimate user based upon the specific use to which the product will be put.

2003 WI App 192, ¶ 21, 266 Wis. 2d 970, 669 N.W.2d 737. Smith & Nephew argues here that the sophisticated user doctrine bars Plaintiff's claim because Dr. Colligan, a sophisticated user of the various components used in hip replacement surgery, was knowledgeable about the risks of using metal components and weighed those risks in choosing the CoCr femoral head he used in Plaintiff's revision surgery.

Again, however, there is a factual dispute that precludes entry of summary judgment in favor of Smith & Nephew on this basis. While Dr. Colligan had some knowledge of the risks of metal toxicity and considered those risks in his decision to use the CoCr head, there is evidence to suggest that he was not aware of the increased magnitude of the risk that arose when a metal, especially a CoCr, femoral ball was used in a revision surgery following a failed ceramic implant. There is also evidence, in the form of Plaintiff's expert witness declarations and reports, that orthopedic surgeons in 2017 were not generally aware of the increased risk and that manufacturers, such as Smith & Nephew, knew or should have had a greater awareness. *See, e.g.*, Mari Truman Am. Decl. ¶ 36, Dkt. No. 52-3 ("Dangers of CoCr heads with XLPE liners after Ceramic failure were not commonly known by orthopedic physicians."). In other words, a factual dispute exists as to whether Dr. Colligan was in fact a sophisticated user with respect to the risks posed by replacing a ceramic femoral head with a CoCr head in a revision surgery performed after the failure of a ceramic component. This factual dispute precludes entry of summary judgment in Smith & Nephew's favor on Plaintiff's failure to warn claim based on the sophisticated user doctrine.

3. Causation

Finally, Smith & Nephew argues that it is entitled to summary judgment on Plaintiff's failure to warn claim because there is no evidence that any failure on its part to warn was a substantial cause of Plaintiff's injuries. "A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury." *Kurer v. Parke, Davis & Co.*, 272 Wis. 2d 390, 404, 679 N.W.2d 867 (Wis. Ct. App. 2004). In support of this argument, Smith & Nephew cites the Seventh Circuit's decision in *Zimmer*, which rejected that plaintiff's failure to warn claim, explaining:

> [The plaintiff] argues that if Zimmer had warned him of a risk of early failure, he would have "heeded the warning and been inclined to choose an implant with a

> known greater longevity." But [the plaintiff] didn't select the NexGen Flex implant. Dr. Larson did, and he made his decision based on his own past experience, not on any marketing materials or information provided by Zimmer.

884 F.3d at 752. Smith & Nephew argues that the same reasoning applies here. Dr. Colligan, not Plaintiff, selected the CoCr femoral head and XLPE liner for the revision surgery, Smith & Nephew notes, and he did so based on his own experience and training. Indeed, Dr. Colligan did not even read any written materials available from Smith & Nephew.

In further support of its argument, Smith & Nephew cites *Eiter v. Wright Medical Technology Inc.*, in which the court granted summary judgment on the failure to warn claims in a similar case involving implants used in a THA. No. CV-20-00552-PHX-DJH, 2022 WL 4104559 (D. Ariz. Sept. 8, 2022). As in this case, the plaintiff there alleged that the defendant had negligently failed to provide adequate warnings, rendering its product unreasonably dangerous. Also, as in this case, the surgeon had not read, or had no recollection of reading, the IFU for the devices used. The district court concluded that this was fatal to the plaintiff's claims, even assuming the warnings provided were inadequate. If the surgeon did not even read the IFU, the court concluded, the defendant's failure to provide adequate warnings in the IFU could not have caused the plaintiff's harm. *Id.* at *3. The *Eiter* court also concluded from the undisputed evidence that the plaintiff's surgeon was already aware of the risk that allegedly caused plaintiff's injury. *Id.* For this reason, too, the court concluded summary judgment was appropriate.

The facts of this case are distinguishable from those in *Zimmer* and *Eiter*, however, in several respects. First, as noted above, there is evidence that Dr. Colligan and other surgeons were not aware of the magnitude of the risk to their patients' health that using a CoCr femoral head in revising a failed ceramic component of a THA would pose. Plaintiff's experts, as well as Dr. Lewallen, who performed Plaintiff's second revision surgery, have opined that orthopedic

physicians were not commonly aware of the dangers posed by using CoCr heads with XLPE liners after failure of a ceramic component. Truman Decl. ¶ 36; Kantor Decl. ¶ 13; Lewallen Dep. at 18:09–19:17. Evidently, Smith & Nephew was recommending the use of metal head replacements following ceramic failures until mid-2016, and only then began changing its IFUs and Surgical Technique brochures. Truman Decl. ¶¶ 8, 17–18. The mere fact that Dr. Colligan was generally aware of some degree of risk in using a metal head in the revision surgery does not insulate Smith & Nephew from liability for failing to effectively warn surgeons of the catastrophic consequences of using a CoCr head that it became aware of in the years before Plaintiff's first revision surgery.

The facts of this case also differ from those of *Eiter* in that, in this case, the IFU was not the only means of warning physicians about the risks of using a CoCr head in revising a failed ceramic THA, especially considering that, up until mid-2016, Smith & Nephew had been recommending the use of metal heads in that context. Here, there is evidence that Smith & Nephew failed to promptly take the necessary steps to ensure that orthopedic surgeons performing revision surgeries for hip replacements as a result of the failure of ceramic components were warned of the dangers of using CoCr femoral heads due to the increased risk of wear from the ceramic debris that inevitably remained after fracture. Ms. Truman states in her report that Smith & Nephew should have been advising surgeons of the hazards of using CoCr heads with XLPE liners after a ceramic failure no later than 2014 based upon the information it had. Truman Report at 39. Truman also opined that, given the magnitude of the risk, Smith & Nephew should have sent letters directly to physicians using its hip systems and had systems in place, including on its sales staff, to make sure orthopedic surgeons were aware of the danger. *Id.* Neither Dr. Colligan, nor St. Mary's Hospital, received the Advisory Notice or the Surgical Technique brochure prior to Plaintiff's revision surgery.

As noted above, Smith & Nephew also retained a sales representative in the Green Bay area who would typically speak with a surgeon who was planning on using a Smith & Nephew implant. While a medical device manufacturer's sales representative may not usurp a surgeon's medical judgment, he arguably has a duty, as a representative of the manufacturer, to warn the surgeon of significant risks arising from a proposed use of the device of which the surgeon is unaware. Jon Bjelde, Smith & Nephew's sales representative for the Green Bay area, testified that he advised Dr. Colligan to use a ceramic head on a fresh femoral stem taper for revising a failed ceramic implant. PSSOF ¶ 65. However, Dr. Colligan denies such a warning was ever provided.

Smith & Nephew notes that Dr. Colligan testified that he did not recall having a conversation with Mr. Bjelde. Colligan Dep. at 30:25–31:02, 72:02–05. A lack of recollection, Smith & Nephew argues, is not a denial and thus Bjelde's account is undisputed. But Dr. Colligan also denied that Bjelde ever conveyed such a warning and further testified that if such a warning had been given to him by Smith & Nephew, he would not have proceeded with using the CoCr femoral head in the revision surgery. *Id.* at 156:11–57:22. This is sufficient to create a factual dispute. Lacking a recollection of a conversation is not inconsistent with being certain specific information was not conveyed if the information allegedly conveyed is such that it would have spurred a reaction.

Even assuming that Dr. Colligan was causally negligent in failing to recognize the risk in using a CoCr femoral head in this context, this would not preclude a jury from finding that Smith & Nephew was also causally liable for failing to effectively issue warnings highlighting the potential danger in using its product under such circumstances. Under Wisconsin law, there can be more than one cause of an injury. A failure to more effectively warn of risks associated with foreseeable uses of a manufacturer's products can combine with the negligence of a physician to

cause a plaintiff's injury. *See* Wis. Stat. § 895.045(3). In light of the evidence of Smith & Nephew's failure to effectively warn surgeons of the risks involved, Dr. Colligan's testimony that he would not have used a CoCr femoral head in Plaintiff's revision surgery had he known that Smith & Nephew recommended against their use in cases such as Plaintiff's is enough to create a jury question. Smith & Nephew is therefore not entitled to summary judgment on Plaintiff's failure to warn claim.

E. Negligent Misrepresentation

Plaintiff also asserts a claim for negligent misrepresentation. The elements of negligent misrepresentation are (1) the defendant made a representation of fact; (2) the representation of fact was untrue; (3) the defendant was negligent in making the representation of fact; and (4) the plaintiff believed the representation of fact to be true and relied upon it to his or her damage. *Skyrise Constr. Group, LLC v. Annex Constr., LLC*, 956 F.3d 950, 959–60 (7th Cir. 2020) (citing *Malzewski v. Rapkin*, 2006 WI App 183, ¶ 20, 296 Wis. 2d 98, 723 N.W.2d 156); *accord* Wis JI-Civil 2403. Smith & Nephew asserts that Plaintiff cannot make out a claim for negligent misrepresentation because she has not shown that she relied, or would have relied, on a representation of fact made by Smith & Nephew that resulted in harm to her.

In order to assess Smith & Nephew's argument, it is first necessary to identify the misrepresentation or misrepresentations Smith & Nephew allegedly made. Plaintiff alleges that "Smith & Nephew consistently under-reported and withheld information about the likelihood of the CoCr-XLPE Articulation after ceramic failure to fail and cause injury and complications, and has misrepresented the efficacy and safety of the same products, actively misleading the FDA, medical community, patients, the public at large, and Plaintiff." Compl. at ¶ 99. In other words, Plaintiff alleges that Smith & Nephew failed to disclose the magnitude of the risk associated with

using a CoCr femoral head in the case of revision due to fracture of a ceramic component of a THA. Under Wisconsin law, a nondisclosure is actionable as a misrepresentation tort if there is a duty to disclose. *Tietsworth v. Harley-Davidson, Inc.*, 2004 WI 32, ¶ 12, 270 Wis. 2d 146, 677 N.W.2d 233 (citing *Ollerman v. O'Rourke Co., Inc.*, 94 Wis. 2d 17, 26, 288 N.W.2d 95 (1980)). "A manufacturer has a duty to warn customers or users of defective conditions which may render its products unreasonably dangerous, as well as of any risks of injury that may be associated with its products." *Gracyalny v. Westinghouse Elec. Corp.*, 723 F.2d 1311, 1318 (7th Cir. 1983) (applying Wisconsin law); *see also Kozlowski v. John E. Smith's Sons Co.*, 87 Wis. 2d 882, 898–99, 275 N.W.2d 915 (1979). Thus, it would appear that if Smith & Nephew negligently failed to disclose the magnitude of the risk associated with using a CoCr femoral head to replace a ceramic head following failure of a ceramic component used in a THA, Plaintiff may be able to show an actionable misrepresentation.

Smith & Nephew, however, does not here argue that its failure to disclose such risk is not actionable as a matter of law. Instead, it argues that it is the absence of evidence of reliance by Plaintiff that warrants summary judgment in its favor. Summary judgment should be granted as to this claim, Smith & Nephew argues, "because there is no evidence that Plaintiff relied upon any representations made by Smith & Nephew." Def.'s Br. at 22. In fact, Plaintiff never interacted with Smith & Nephew or read any of its literature. It is undisputed that Plaintiff trusted and relied upon Dr. Colligan's medical judgment to make the appropriate decisions regarding her care, including which components to implant during the revision surgery of her left hip, and that she did not undertake any independent research regarding the components to be used. DSOPMF ¶¶ 33–34. As a result, Smith & Nephew maintains, Plaintiff did not rely upon any representation of fact made by Smith & Nephew, and her negligent misrepresentation claim must fail.

Admittedly, the law is not entirely clear on this issue, and it is unclear what a claim of negligent misrepresentation adds to Plaintiff's case. The fact that Plaintiff had no direct interaction with Smith & Nephew, however, does not mean that Plaintiff could not have relied upon any misrepresentation Smith & Nephew might have made, either affirmatively or by omission. Wisconsin courts have adopted the Restatement of the Law of Torts, which states in this connection:

> The maker of a fraudulent misrepresentation is subject to liability for pecuniary loss to another who acts in justifiable reliance upon it if the misrepresentation, although not made directly to the other, is made to a third person and the maker intends or has reason to expect that its terms will be repeated or its substance communicated to the other, and that it will influence his conduct in the transaction or type of transaction involved.

RESTATEMENT (SECOND) OF TORTS § 533 (1977); *see also Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 971–72 (E.D. Wis. 2009) ("It is wholly foreseeable to a drug manufacturer that its prescribing and side effect information will be communicated to and relied upon by patients, even when the drug company only interacts directly with prescribing physicians and not patients. Though GSK made no direct representations to the plaintiffs, the plaintiffs based their decisions regarding Paxil on the information and advice of Dr. Todd. . . . This information, in turn, was based upon GSK representations. Therefore, a genuine issue of material fact exists regarding whether Dr. Todd and the plaintiffs relied upon GSK's alleged misrepresentations."). Here, Plaintiff argues that Smith & Nephew's failure to disclose the risks attendant upon using a CoCr femoral head under the circumstances of her case constitutes a material misrepresentation. Had Smith & Nephew disclosed such information to her and her physician, Plaintiff contends, Dr. Colligan would not have recommended and "she would not have allowed the troubling components to be used." Pl.'s Br. at 27. This is sufficient, at least at this stage and on this record, to show reliance and allow Plaintiff's negligent representation claim to proceed.

In support of its argument that Plaintiff's negligent misrepresentation claim should be dismissed, Smith & Nephew cites *Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273 (E.D. Wis. May 12, 1999). In *Monson*, the plaintiff sought to recover damages arising out of the implantation of a spinal fixation system utilizing pedicle screws (spinal fixation device). Among the claims asserted against the manufacturer of the device were claims for fraud, false advertising, and intentional concealment. The plaintiff alleged that the manufacturer of the pedicle screws "utilized the advertising media to urge the use of internal spinal fixation devices and intentionally failed to warn the FDA, physicians, and the general public concerning lack of adequate testing of the safety of the implants, and . . . failed to report any known adverse effects of the internal spinal fixation devices to the general public; and . . . prepared brochures and advertisements knowing or having reason to know the falsity thereof." *Id.* at *22 (internal quotation marks omitted). The district court concluded, however, that there was no evidence that defendants made any representations to the plaintiff. Instead, the plaintiff's own doctor had provided to plaintiff the very information he alleged that the defendant manufacturer had failed to disclose. *Id.* at *23. On the basis of this record, the district court concluded that "there is no material issue of fact regarding reasonable reliance for the jury." *Id.* (citation omitted).

The same is not true here. Dr. Colligan did not supply the information Plaintiff contends Smith & Nephew omitted in its representations about its products. If those omissions constitute material misrepresentations, a jury could conclude that Plaintiff, as well as Dr. Colligan, relied upon them. Absent further development of the record, Smith & Nephew's motion will be denied as to Plaintiff's claim for negligent misrepresentation.

CONCLUSION

For the foregoing reasons, Smith & Nephew's motion for partial summary judgment (Dkt. No. 30) is **GRANTED-IN-PART** and **DENIED-IN-PART**. The motion is granted with respect to Plaintiff's claims of breach of express warranty and breach of implied warranty, and those claims are dismissed. The motion is denied as to Plaintiff's negligent failure to warn and negligent misrepresentation claims. The court further concludes that, reasonably construed, the complaint also states a product liability claim.

SO ORDERED at Green Bay, Wisconsin this 7th day of February, 2023.

s/ William C. Griesbach
William C. Griesbach
United States District Judge